Applicant: POLY-MED, INC. Attorney's Docket No.: 00537-183002 / BPC 076

Serial No.: 09/762,431 Filed: February 7, 2001

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<u>REMARKS</u>

This Reply is being filed concurrently with a Request for Continued Examination under 37 C.F.R. § 1.114. Applicants respectfully request non-entry of the claim amendments submitted with the Reply filed on February 20, 2004.

Claims 2-28 are pending. Claims 2-10 and 13-28 are canceled without prejudice to their presentation in a later filed application claiming the benefit of priority of the present application. Claims 11 and 12 are therefore pending in the application.

Claim 11 has been amended as follows. Applicants have rewritten claim 11 in independent form. Accordingly, claim 11 has been amended to explicitly recite the limitations of base claim 1. Applicants have also inserted the phrase "wherein said monophosphate functionality comprises a -O-P(O)(OH)₂ moiety covalently-linked to said polyester chain via by a single phosphate bond, and "immediately before the recitation of "wherein the polyester chain comprises..." Support for this amendment can be found throughout the Specification, e.g., at page 5, lines 27-30, wherein the term "monophosphate functionality" is defined; and at page 8, lines 3-21, more particularly lines 18-19, wherein the insertion of the -O-P(O)(OH)₂ moiety is discussed.

No new matter has been introduced by these amendments.

Claims 11, 12, and 19 have been rejected under 35 U.S.C. § 112, second paragraph for being indefinite. This rejection is moot in view of the amendment of claim 11 and cancellation of claim 19.

Claims 11 and 19 have been rejected under 35 U.S.C. § 102 (a) or (e) as being anticipated by Kakizawa et al., U.S. Patent 5,686,540 (Kakizawa). According to the Examiner:

Kakizawa exemplifies a lactic acid-based polyester comprising L-lactide/D-lactide (98/2), terephthalic acid, ethylene glycol, and tartaric acid. See Col. 19, lines 40-64. It is respectfully pointed out that the limitations in the preamble of claim 11 of an absorbable polyester ... do not render the claims patentable (Office Action, page 3, lines 18-19 and lines 20-22).

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Claims 11 and 19 were <u>finally</u> rejected in the present Office Action as being anticipated by Kakizawa (claim 12 was also finally rejected under 35 U.S.C. 103(a)). Applicants wish to point out that Kakizawa was not cited in the non-final Office Action dated November 20, 2002, nor was Kakizawa cited by Applicants in an Information Disclosure Statement submitted during the time period set forth in 37 C.F.R. 1.97 (c). Therefore, Applicants respectfully submit that Kakizawa constitutes a new ground for rejection.

The rejection of claim 19 is moot in view of its cancellation.

Applicants respectfully traverse with respect to pending claim 11. The preamble of claim 11 as originally filed recites "[a]n absorbable polyester according to claim 1." Accordingly, the absorbable polyesters covered by claim 11 are absorbable polyesters "with at least one monophosphate functionality per absorbable polyester chain." Thus, the preamble of claim 11 sets forth the structural limitation that the absorbable polyester is covalently linked to a phosphoric acid by a single phosphate bond (see Specification, e.g., at page 5, lines 27-30). According to the MPEP:

Any terminology in the preamble that <u>limits the structure</u> of the claimed invention must be treated as a <u>claim limitation</u>. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (MPEP § 2111.02, emphasis added).

Applicants submit that the phrase "with at least one monophosphate functionality per absorbable polyester chain" should therefore be treated as a claim limitation and accorded patentable weight in the examination of claim 11 and claims depending therefrom.

There is no disclosure anywhere in Kakizawa, let alone in the passage from Kakizawa cited in the Office Action, of an absorbable polyester with at least one **monophosphate**functionality per absorbable polyester chain (i.e., an absorbable polyester covalently linked to a phosphoric acid), as is required by claim 11. Therefore, Kakizawa does not anticipate claim 11. Applicants respectfully request withdrawal of the rejection.

Claim 12 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Kakizawa as applied to claims 11 and 19.

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Applicants respectfully disagree. As discussed above, Kakizawa does not teach absorbable polyesters with at least one monophosphate functionality per absorbable polyester chain, which is required by claim 11. Further, there is no suggestion or motivation in Kakizawa to modify the Kakizawa polymers to include a covalent linkage to a phosphoric acid. Claim 11 is therefore not obvious over Kakizawa. Since claim 12 depends from claim 11, it also is not obvious over Kakizawa. Applicants respectfully request withdrawal of the rejection.

Finally, Applicants wish to address remarks made in the Reply filed on February 20, 2004, specifically the statement "[t]he pending claims of the instant application contain a limitation, i.e. that terephthalic acid and ethylene glycol **are not present** in the claimed polyester chain," (Applicants' Reply dated February 20, 2004, page 11, lines 10-13, emphasis in original). It was Applicants' intent to point out that terephthalic acid and ethylene glycol were not included in the Markush group recited in claim 11. However, Applicants wish to clarify that "terephthalic acid" and "ethylene glycol" are not excluded from claim 11 by virtue of the open-ended transitional phrase "comprising" in the phrase "wherein the polyester chain comprises one or more monomers selected from the group consisting of..."

Applicants submit that the foregoing amendments and remarks are responsive within the meaning of 37 C.F.R. 1.111, and therefore this Reply meets the requirements of a submission under 37 C.F.R. 1.114.

Applicants ask that all claims be examined and allowed.

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Enclosed is a \$1,480 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No.: 00537-183002.

Respectfully submitted,

Date: August 20, 2004

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804

Telephone: (617) 542-5070 Facsimile: (617) 542-8906

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John T. Kendall, Ph.D.

Reg. No. 50,680